IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9024

Bartle, J. March 7, 2013

Kathy Causey ("Ms. Causey" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Christopher D. Causey and Rhett E. Causey, Ms. Causey's children, also have submitted derivative claims for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Milton Concannon, M.D. Based on an echocardiogram dated December 14, 2002, Dr. Concannon attested in Part II of Ms. Causey's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Concannon also attested that claimant suffered from mild aortic regurgitation. This condition is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $538,973.[5]

In the report of claimant's echocardiogram, Dr. Concannon stated, "There is moderate (31%) mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2005, the Trust forwarded the claim for review by Alyson N. Owen, M.D., one of its auditing cardiologists. In audit, Dr. Owen concluded that there was no reasonable medical basis for Dr. Concannon's finding that claimant had moderate mitral regurgitation. In support, Dr. Owen explained:

> Visually there is mild, posteriorly directed [mitral regurgitation]. Color is difficult to assess being significantly overgained with too much color saturation. The first jet they draw in the apical 4 chamber is 3.43 with a LAA of 16.86 which gives [a] 20% ratio, but the jet is overdrawn, including low velocity blue which does not appear to be [part] of the jet. Later they overdraw even

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5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II mitral valve claim, the only issue is claimant's level of mitral regurgitation.

more significantly, including low velocity blue in the pulmonary veins.

Dr. Owen also stated, "Color Doppler is overgained. What is drawn is a mixture of actual jet and artifact."

Based on Dr. Owen's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Causey's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that the auditing cardiologist should have deferred to Dr. Concannon because Dr. Owen stated that the "[c]olor is difficult to assess being significantly overgained with too much color saturation" while Dr. Concannon did not identify this impediment. Claimant also asserted that the auditing cardiologist's reference to the attesting physician's measurement of 20% purportedly reveals that "the auditing cardiologist's [sic] was reviewing the incorrect echocardiogram or was confused." In addition, claimant asserted that "[a]ll measurements that are close to the abnormal range, or grossly different should require greater deference to the treating doctors [sic] opinion, because he actually treated the claimant in person and was in a better position to assess her

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Causey's claim.

condition." Finally, claimant maintained that the auditing cardiologist's finding of a mildly dilated left atrium is suspect and an arbitrary attempt to deny the claim.

The Trust then issued a final post-audit determination again denying Ms. Causey's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Causey's claim should be paid. On August 2, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6455 (Aug. 2, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant reasserts many of the arguments raised during contest. In addition, she argues that Dr. Concannon's opinion is entitled to greater weight than the auditing cardiologist's because Dr. Concannon "is an unbiased professional whose practice has only minimal involvement in the Phen-Fen litigation."

In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because

claimant did not rebut any of the auditing cardiologist's specific findings. The Trust also asserts that claimant cannot prevail on her claim because the deficiencies identified by the auditing cardiologist constitute impermissible conduct identified previously by the court in PTO No. 2640 (Nov. 14, 2002).

The Technical Advisor, Dr. Vigilante, reviewed claimant's record and echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Causey had moderate mitral regurgitation. In support, Dr. Vigilante explained:

> [T]his study was not performed in accordance with the usual standards of care. There was significantly increased color gain and color artifact noted particularly in the apical views. There was color artifact noted outside of the cardiac chambers. However, discreet mitral regurgitant jets could be seen in the mid portion of systole....
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> .... Visually, a mild jet of mitral regurgitation was noted traveling posterolaterally within the left atrium on both the parasternal long-axis and apical views. I digitized those cardiac cycles in the apical views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. In spite of excessive color gain and color artifact, I was able to accurately planimeter the RJA in the mid portion of systole. The largest representative RJA was 1.7 cm2 in the apical four chamber view. I determined that the LAA was 16.7 cm2 in the apical four chamber view. Therefore, the largest RJA/LAA ratio in the apical four chamber view was 10% qualifying for mild mitral regurgitation. I determined that the largest representative RJA in the mid portion of systole in the apical two chamber view was 1.4 cm2. The LAA in the apical two chamber view was 16.8 cm2. Therefore, the largest

> RJA/LAA ratio in the apical two chamber view was 8%. None of the RJA/LAA ratio determinations came close to approaching 20%. The sonographer planimetered a supposed RJA in the apical four chamber view at 3.43 cm2. This was completely inaccurate as it was performed at the beginning of systole and contained a great deal of low velocity and non-mitral regurgitant flow. The sonographer's LAA determination of 16.81 cm2 in the apical four chamber view was similar to my LAA measurement of 16.7 cm2. The sonographer measured a supposed RJA of 6.29 cm2 in the apical two chamber view. This measurement was completely inaccurate as it contained non-mitral regurgitant flow. This measurement was performed on artifact and not mitral regurgitation. The sonographer's LAA measurement of 19.91 cm2 was inaccurate as it went beyond the back wall of the left atrium. The inaccurate sonographer RJA and LAA measurements are the same ones noted on the worksheet. The inaccurate RJA and LAA measurements in the apical two chamber view result in an inaccurate RJA/LAA ratio of 31%. This inaccurate ratio was the same value described by Dr. Concannon in his formal echocardiogram report. In summary, the Claimant's echocardiogram of December 15, 2002 demonstrated only mild mitral regurgitation.

In response to the Technical Advisor Report, claimant reasserts the arguments she raised in contest. Claimant also argues that Dr. Vigilante's reading of the December 14, 2002 echocardiogram should be disregarded because it was "grossly different from the other two doctors." According to Claimant, the RJA/LAA ratio Dr. Vigilante calculated was one-half the calculation of the auditing cardiologist and one-third the calculation of the attesting physician and Dr. Vigilante's left atrium measurement was one-half of the measurement obtained by both the auditing cardiologist and the attesting physician.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the finding of Dr. Owen that Ms. Causey had only mild mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Causey rests only on Dr. Concannon's check-the-box diagnosis on her Green Form. Nor does Ms. Causey specifically refute or respond to the fact that the Trust's auditing cardiologist determined that the echocardiogram at issue does not establish moderate mitral regurgitation because the mitral regurgitation jet areas were "overdrawn" and improperly included low velocity area and artifact, which the auditing cardiologist concluded was not properly part of the mitral regurgitant jet area. Mere disagreement with the auditing cardiologist without identification of specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that Dr. Concannon's interpretation provides a reasonable medical basis for his Green Form representation or that his opinion is entitled to more weight. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple

loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26.

Here, Dr. Owen determined in audit, and Ms. Causey does not adequately dispute, that Dr. Concannon's finding of moderate mitral regurgitation was based on overtracing the amount of claimant's mitral regurgitation and improperly including low velocity areas and artifact in determining the level of mitral regurgitation, resulting in an erroneous diagnosis of moderate mitral regurgitation. In addition, Dr. Vigilante determined that claimant's study demonstrated significantly increased color gain and color artifact. Dr. Vigilante also observed that the sonographer's supposed RJA measurement of 3.43 cm^2 in the apical four chamber view was "completely inaccurate as it was performed at the beginning of systole and contained a great deal of low velocity and non-mitral regurgitant flow." In addition, Dr. Vigilante determined that the sonographer's supposed RJA measurement of 6.29 cm^2 in the apical two chamber view was "completely inaccurate as it contained non-mitral regurgitant flow" and contained artifact. Finally, Dr. Vigilante noted that

the sonographer's LAA measurement of 19.91 cm^2 was "inaccurate as it went beyond the back wall of the left atrium."[8] These measurements, Dr. Vigilante observed, are the same ones noted in Dr. Concannon's echocardiogram worksheet and report. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

We also reject claimant's assertion that the attesting physician's interpretation is entitled to more weight because he, unlike the auditing cardiologist and the Technical Advisor, did not indicate the echocardiogram was difficult to interpret. Both the auditing cardiologist and the Technical Advisor noted that claimant's echocardiogram tape was evaluable despite the technical difficulties associated with the study. In fact, the Technical Advisor specifically observed, "In spite of excessive color gain and color artifact, I was able to accurately planimeter the RJA in the mid portion of systole."

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8. We also reject claimant's argument that Dr. Vigilante's conclusions should be disregarded because they are different from those of the attesting physician and the auditing cardiologist. Contrary to claimant's contention, Dr. Owen did not determine Ms. Causey's echocardiogram demonstrated an RJA/LAA of 20%. Dr. Owen noted that the measurements of the sonographer resulted in an RJA/LAA ratio of 20%, but determined that "the jet is overdrawn, including low velocity blue which does not appear to be [part] of the jet." In addition, contrary to Ms. Causey's contention, Dr. Vigilante's left atrium measurement is not one-half that of the attesting physician or auditing cardiologist. The 3.0 cm reference on which Ms. Causey relies is the left atrial antero-posterior diameter. Notably, Dr. Owen and Dr. Vigilante measured claimant's left atrial supero-inferior diameter to be 5.2 cm.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Causey's claim for Matrix Benefits and the related derivative claims submitted by her children.